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Safety of homeopathic products

'It must be safe—it's homeopathic'. Comments of this sort from medical practitioners and the public are common—but are they correct? Homeopathy arose as a response to the often complex, and sometimes hazardous, therapeutics existing in the 18th century. Hahnemann formulated a new system of therapeutics based on the idea that substances simulating the symptoms of illness could aid the natural healing of the body. He also asserted that the therapeutic effect was retained even in high dilution, thereby avoiding the potential for adverse effects observed in conventional therapy. Controversy has dogged homeopathy ever since—particularly on the question whether these high dilutions, defying conventional scientific principles, could possibly have any therapeutic effect whatsoever. Homeopaths have claimed that their method of preparing dilutions imparts qualities that retain the therapeutic effect[1]. Many clinical studies have been conducted in the hope of either confirming or refuting these contentions but debate on such work, and even on systematic reviews, commonly centres on methodology; so there is continuing uncertainty about the usefulness of homeopathy[2–5]. From the point of view of safety, there is general agreement in both camps that high dilution of a substance greatly reduces the likelihood of adverse effects. What little information exists about safety is reassuring[6] but an absence of reports of serious adverse events does not mean they have not happened—a matter of particular importance with the increase in self-medication. Homeopathy is a fast growing sector accounting for roughly 20% of the complementary and alternative medicine market with a value probably now exceeding £25m per year in the UK.

In the past, most homeopathic preparations were prescribed by a homeopath for an individual after a detailed analysis of the symptoms, nature of the illness, personality and lifestyle, often with arrangements for continued care and follow-up. Certain products, known to homeopaths as *polychrests*, have been widely recognized as effective in certain conditions and patient types; these, supplemented by other homeopathic products, are now purchasable directly by the public without a homeopathic consultation. Neither older preparations on the market before the Medicines Act 1968 nor newer preparations had been subjected to scrutiny until the recent advent of schemes to do so in all the member states of the European Community[7,8]. Because of the difficulties of determining 'efficacy' in the conventional sense, these registration schemes have been limited solely to ensuring a product's safety and quality. This work is done in the UK by the Medicines Control Agency, who refer for advice when necessary to the Advisory Board on the Registration of Homeopathic Products. Members of the Board include homeopathic and non-homeopathic practitioners of medicine and pharmacy, non medically qualified homeopaths, specialists in toxicology, as well as lay members. The Board's work is ably supported by a professionally qualified secretariat.

Most homeopathic products are of plant or natural mineral origin, but some come from animal (including human) sources, and a few, known as *nosodes*, are from diseased tissue or secretions. The related discipline of *isopathy* uses various other starting materials such as pollens and animal hair. Plainly, a vital first step is to establish the source of these starting materials. For example, one wants to know that the plants have been correctly identified, that they have not been adulterated by the inclusion of other species and that they are free from contamination by noxious herbicides. As with any other medicine, each step of the transformation from raw material to final product must be readily traceable. The provenance of some animal materials—such as snake venom, whole insects or specific tissues—can be problematic; and plant material can be hard to identify when it has been dried at source. Fortunately the use of human tissue, including diseased organs, is now decreasing, and products derived from such material are not generally proposed for sale to the public. Even though high dilution can be expected to reduce the risk of transmission of bacterial, viral or prion diseases to almost zero, many people are left with an uneasy feeling that some of these starting materials still present a small hazard.

Although the raw materials may be unconventional, the pharmaceutical methods used to make homeopathic products are similar to those used in conventional pharmacy and many of them are set out in homeopathic and conventional pharmacopoeias[9]. The first step is the preparation of the *mother tincture*—an aqueous/alcohol extract of soluble material from which the dilutions are made. Some solid materials are ground down, or triturated, and then incorporated in lactose-containing powders or tablets. Steps to ensure the quality of the reagents and monitoring of all

steps in the manufacturing process are similar to those applied to other medicines. The major difference of homeopathic products from these others is the progressive dilution of the mother tincture in accordance with homeopathic principles. Briefly, the *centesimal* method entails taking one drop and diluting it with 99 drops of diluent then taking a drop of this into a clean vial and repeating this process six or many more times. At each stage it is *potentized* by vigorous shaking and striking of the container (*succussion*). This is essential to the homeopathic process but why it should be important in retaining the homeopathic properties of the products is unknown. These dilutions are designated *potencies*. Most products on public sale are designated *6c* (meaning that the process has been performed six times, resulting in a dilution of 1 in 100^6) or *30c* (giving 1 in 100^{30}). Once the required dilution has been attained, products are placed in a suitable container, with an indication on the package of the shelf-life and recommended storage conditions. It is not permissible to make any statement about indications for use, since the registration scheme does not assess efficacy. This accounts for the puzzling phenomenon in retail outlets whereby pamphlets describing homeopathic usage are displayed but no information of this sort can be found on the packages or labels of the products themselves.

Sometimes symptoms grow worse transiently when a homeopathic product is used, a phenomenon known to homeopaths as an *aggravation*; but apart from descriptions of these brief, readily reversible, phenomena, there are few records of adverse events arising in the conventional sense. According to conventional toxicology, any toxic substances in a product will be diluted well below hazardous levels. Although some mother tinctures are used undiluted by homeopaths, this is not permitted for products on sale to the public. A theoretical hazard could be failure to dilute sufficiently, or to confuse metric with centesimal dilution, either of which could result in a much higher dose being prepared; there is no record of this happening in any manufactured product. When homeopathic remedies were prescribed on an individual basis an accident of this sort would have affected only one recipient, but the growth of larger scale manufacturing means that a fault in the production process could have a much wider effect. Manufacturers of homeopathic products are well aware of the potential for manufacturing errors and adhere to international guidelines on production monitoring just as assiduously as other pharmaceutical manufacturers.

Even though the hazards from homeopathic products are modest in comparison with those of conventional medicines, the fast-growing popularity of homeopathy and its increasing use for self-medication signify the need for continued vigilance to ensure the quality and safety of products directly available to the consumer.

Note: Professor Kirby is chairman of the Advisory Board on the Registration of Homeopathic Products, but the views expressed here are personal.

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